PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Mizzer et al		Docket: DCS-9129
Filed:	18-July-2003	Group Art Unit: 1743
Serial No.:	10/623,355	Examiner: Soderquist, Arlen
Title:	Method For Increasing Capacity In An Automatic Clinical Analyzer By Using Modular Reagent Delivery Means	

Commissioner of Patents
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AFFADAVIT UNDER 37 CFR 1.132

Sir:

I, Peter L. Gebrian, declare that:

1. That I hold a degree in Mechanical Engineering, from Northeastern University, awarded 1974, and that I have been active in the field of designing automated clinical and mechanical equipment for the past 35 years. Major new equipment projects completed successfully include DuPont's Riston™ Laminator and Dimension® RxL Analyzer, and Dade Behring's Ramses™ Microbiological Analyzer, and Dimension® Vista™ Clinical Analyzer.

2. That I am a sole or joint inventor of the subject matter of 17 U. S. patents issued covering subject matter in the field of automated clinical and/or instrumentation devices. See Appendix A. As such, I consider myself to be skilled in the art of designing of automated instrumentation.

3. That I have reviewed and understand the contents of the above identified application, including the claims and all amendments thereto. In particular, I have analyzed paragraphs [0023], [0027], [0029], [0030], Claim 6 and the Abstract attached as Appendix B.

4. That the patent disclosure, in particular paragraph [0030], teaches that less than the full number of available cuvette ports 20 in carousel 14 have cuvettes 24 disposed therein, as shown in FIG. 2. Further, to one skilled in the art, the example given in the Abstract of 50% of cuvette ports 20 being filled would be understood as a single exemplary illustration of the more general concept of initially underutilizing the cuvette ports 20 and then increasing useage as throughput limiting resources were added.

5. That the patent disclosure would clearly and easily be understood by one skilled in the art to mean that all of the assay resource devices required to perform assays on analyzer 10 (such as sensors, mixing stations, separation stations, transport systems and the like), other than the throughput limiting reagent resources, are initially installed on the analyzer to operate in a normal manner and they are by design not throughput limiting. See paragraph [0010] and claim 6, teaching that, "the analyzer is further initially configured such that the operating resources which are not throughput limiting are also initially adapted to accommodate the addition of throughput limiting resources."

6. That from the application's disclosure of the full number of cuvette ports 20 being underutilized in the analyzer's initial configuration, taken with item 6, it is clear to an artesian that the analyzer is initially configured with all of the assay resources required to perform assays on analyzer 10, other than the through-put limiting reagent resources, with a sufficiently high capacity or throughput level, and that the analyzer is then operated at lower capacity or throughput level.

7. That the patent disclosure identified above would fully enable one skilled in the art to increase the throughput of a clinical analyzer, as claimed, by:
   - initially configuring the analyzer with reagent resources to conduct a group of assays, these reagent resources being throughput limiting;
   - initially configuring the analyzer with all other assay resources required to conduct said group of assays, the other assay resources not being throughput limiting; and,
   - incrementally adding reagent resources to the analyzer in order to increase throughput as the number of assays to be conducted increases.

8. That all statements made herein of my own knowledge are true and that all statements made on belief and information are believed to be true.

9. That I have been warned that willful false statements and the like are punishable by fine or imprisonment or both (18 USC 1001) and may jeopardize the validity of the above identified application or any patent issuing thereon.

7-5-07
Date

Peter L. Gebrian

APPENDIX A

U. S. Pat. No.	Title
4,495,014	Laminating and trimming process
5,517,867	Liquid extraction apparatus
5,813,759	Method and apparatus for vortex mixing using centrifugal force
6,382,827	Method and apparatus for mixing liquid solutions using a rotating magnet to generate a stirring vortex action
6,467,946	Method and apparatus for mixing liquid samples in a container using rotating magnetic fields
6,573,088	Automated random access microbiological analyzer
6,627,432	Liquid flow and control in a biological test array
6,632,654	Canister for inventorying susceptability test devices in an automated microbiological analyzer
6,653,122	Indentification test device in a random access microbiological analyzer
D482,454	Multi-compartment reagent container for containing reagents
D484,989	Multi-well liquid container
6,776,966	Canister for inventorying identification test devices in an automated microbiological analyzer
6,808,304	Method for mixing liquid samples using a linear oscillation stroke
6,855,540	Reagent container and canister for use in an automated microbiological analyzer
6,943,030	Multi-compartment reagent container having means to inhibit re-use thereof
7,169,356	Random access reagent delivery system for use in an automatic clinical analyzer
7,207,913	Bi-directional drivebelt tensioning device

APPENDIX B

[0023] Sampling arm 44 supports a liquid sampling probe 46 mounted to a rotatable shaft 48 so that movement of sampling arm 44 describes an arc intersecting the sample tube transport system 36 and an aliquot vessel array transport system 50, as seen in FIG. 3. Sampling arm 44 is operable to aspirate liquid sample from sample tubes 40 and to dispense an aliquot sample into one or more of a plurality of vessels 52V in aliquot vessel array 52, as seen in FIG. 4, depending on the quantity of sample required to perform the requisite assays and to provide for a sample aliquot to be retained by analyzer 10 within environmental chamber 38. It is important in the present teaching that analyzer 10 be originally designed and configured so that space and other assay operational devices are also initially adapted to accommodate the addition of throughput limiting resources. (Underlining added for emphasis.)

[0027] The present invention is based on the discovery that analyzer 10 may be initially configured so that whatever operating resources are throughput limiting, those resources are adapted to be incrementally added, for example in a modular fashion, to analyzer 10 as the incoming assay demand increases. (Underlining added for emphasis.)

[0029] A key feature of the present invention is the discovery that the throughput of analyzer 10 may be essentially doubled by adding only an additional reagent storage area 27 operating independently from the existing reagent storage area 26, while at the same time, the useage of cuvette ports 20 available for reaction vessels 24 is also increased. Clearly, addition reagent aspiration and dispense arms 61A and 61B similar to arms 60A and 60B described above are also installed so as to transfer reagents between reagent storage area 27 and cuvette ports 20. (Underlining added for emphasis.)

[0030] An even further increase in the throughput of analyzer 10 may be achieved by the addition of a third reagent storage area 28 as seen in FIG. 7 and operating independently from the two existing reagent storage areas 26 and 27, again increasing useage of cuvette ports 20 available for reaction vessels 24. This further increase in throughput of analyzer 10 by adding additional reagent storage area 28 and at least one

reagent aspiration and dispense arm 62 with probe 62P similar to arms 60A and 60B described above are also installed transfer reagents between reagent storage area 28 and cuvette ports 20. This method of increasing the throughput of analyzer 10 by initially configuring analyzer 10 such that the full number of available cuvette ports 20 is underutilized and then increasing the throughput of analyzer 10 with modular resource additions as the incoming assay demand increases is cost-effectively advantageous to an expanding clinical laboratory. The particular embodiment described here is illustrative of the more general teaching of the present invention in that clinical analyzer 10 may be initially configured so that whatever operating resources are throughput limiting, those resources are adapted to be incrementally added, for example in a modular fashion, to analyzer 10 as the incoming assay demand increases. It is important in such teaching that analyzer 10 be originally designed and configured so that space and other assay operational devices, for instance incoming and outgoing sample tube transport system 36 like seen in FIG. 5, are also initially adapted to accommodate the addition of throughput limiting resources. (Underlining added for emphasis.)

Claim 6. The method of claim 1 wherein the analyzer is further initially configured such that the operating resources which are not throughput limiting are also initially adapted to accommodate the addition of throughput limiting resources. (Underlining added for emphasis.)

ABSTRACT

An automatic clinical analyzer in which the number of cuvette ports available for reaction vessels on a reaction carousel are 50% in a configuration using a single reagent storage areas; in a second configuration an additional reagent storage areas is employed and additional ones of the cuvette ports on reaction carousel are utilized, thereby significantly increasing throughput. (Underlining added for emphasis.)